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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/535,129

05/13/2005

Tetsuya Sakata

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EXAMINER

SZPIRA, JULIE ANN

ART UNIT

PAPER NUMBER

3731

MAIL DATE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/535,129	Applicant(s) SAKATA, TETSUYA	
	Examiner JULIE A. SZPIRA	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 16-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 May 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/13/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Species A, claims 1-15 in the reply filed on 7/1/2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 16-23 are withdrawn from consideration.

Priority

2. Receipt is acknowledged of a certified copy of the PCT/JP03/14398 application referred to in the oath or declaration or in an application data sheet. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. **Claims 1-15** is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In lines 14-15 of claim 1 and lines 17-18 of claim 14, applicant describes the lancing element being capable of projecting from the *lancing element*, and later, in lines 16-18 of claim 1 and lines 17-19 of claim 14 describe the lancing element being accommodated in the second member without projection from the *second member*. The specification and drawings support the claim of the second

member being accommodated without projection from the second member, however does not support the lancing element projecting from the lancing element. Examiner is interpreting the claim to read "the lancing element being capable of projecting from the *second member*". Appropriate correction to the claim is required upon amendment.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

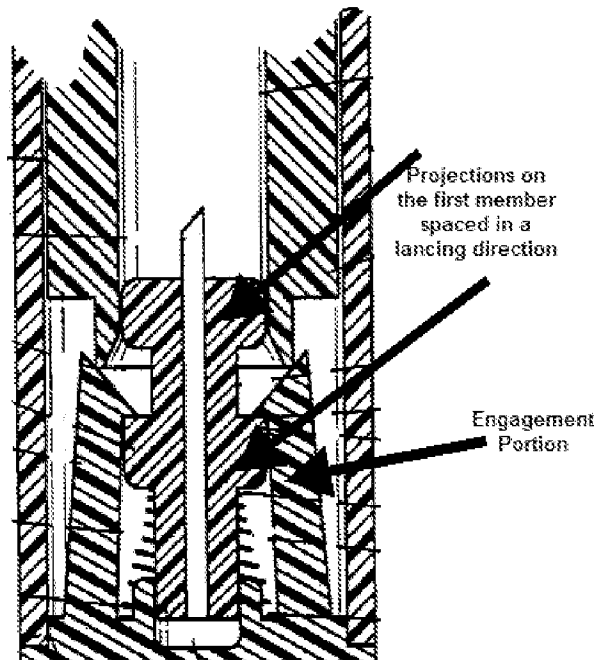
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. **Claims 1-3 and 6** are rejected under 35 U.S.C. 102(b) as being anticipated by **Ramel (US 5,540,709)**.

Regarding claim 1, Ramel discloses a lancet to be attached to a lancing apparatus for moving a lancing element (needle, 4) in a lancing direction from a standby position toward a lance position, the lancet comprising a first member (2) including a lancing element (4) and a second member (42, 18) for accommodating a tip of the lancing element, the first member and the second member being movable relative to each other (column 3, lines 27-33); wherein when a load greater than a predetermined value is applied in a direction to cause the first member and the second member to approach each other, the first member is brought closer to the second member so that the tip of the lancing element is capable of projecting from the lancing element (Figure 7), whereas when the first member is brought away from the second member, the tip of

the lancing element is accommodated in the second member without projecting from the second member (Figure 8).

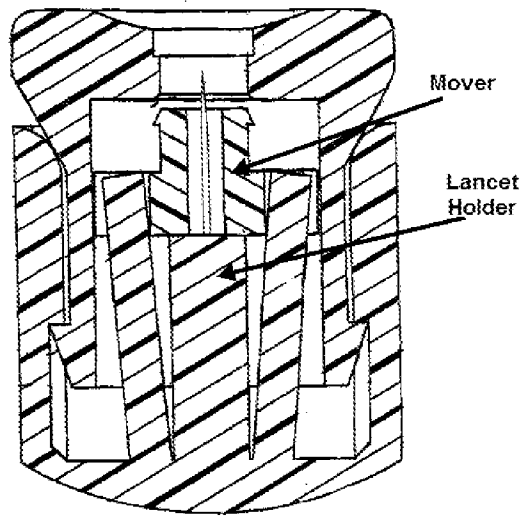
Regarding claims 2 and 3, Ramel discloses the fixer comprises a pair of projections which project at the first member in a direction crossing the lancing direction and which are spaced from each other in the lancing direction (see figure below) and an engagement portion (18) provided at the second member to be held between the paired projections.



Regarding claim 6, Ramel discloses the projections being on the shaft and the shaft being circular (annular), therefore the projections would be annular as well (column 4, lines 56-58).

7. **Claim 14** is rejected under 35 U.S.C. 102(b) as being anticipated by **Searle et al.** (US 2002/0087180 A1).

Regarding claim 14, Searle et al. discloses a lancing apparatus which is used by mounting a lancet and which moves the lancet in a lancing direction from a standby position toward a lance position; the lancet comprising a first member (12) including a lancing element (14) and a second member (16) for accommodating a tip of the lancing element, the first member and the second member being movable relative to each other, wherein when a load greater than a predetermined value is applied in a direction to cause the first member and the second member to approach each other, the first member is brought closer to the second member so that the tip of the lancing element is capable of projecting from the lancing element (paragraph 26, all lines), whereas when the first member is brought away from the second member, the tip of the lancing element is accommodated in the second member without projecting from the second member (Figure 9), the lancing apparatus comprising: a lancet holder (See Below) for holding the lancet, the lancet holder being movable in the lancing direction; and a mover (18) which is movable relative to the lancet holder for moving the second member relative to the first member in the lancing direction, and for causing the tip of the lancing element projecting from the second member to be brought into the second member to be accommodated therein (Figures 8 & 9; See Figure Below).



Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. **Claim 4** is rejected under 35 U.S.C. 103(a) as being unpatentable over **Ramel (US 5,540,709)**.

Regarding Claim 4, Ramel discloses the invention substantially as claimed above, but fails to disclose the second projection that projects more than the first projection.

It would have been an obvious matter of design choice to make one projection larger than the other, since it has been held that a change in size is a matter of design choice and is generally recognized to be within the level of ordinary skill in the art. In re Rose, 105 USPQ 237.

11. **Claims 5 and 7-9** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Ramel (US 5,540,709)** in view of **Searle et al (US 2002/0087180 A1)**.

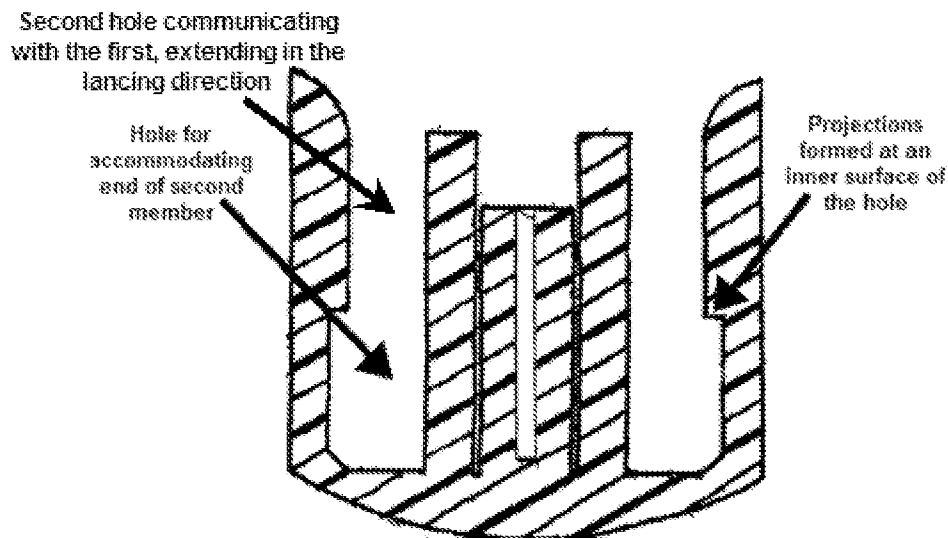
Regarding claim 5, Ramel discloses the invention substantially as claimed above, but fails to disclose the second projection serving as a stopper.

However, Searle et al. teaches a first member with a projection (formed by undercuts, 32) that serves as a stopper to engage with the engagement portion (38) of the second member (16) (paragraph 23, lines 3-5).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a projection to engage the second member to the first member when the second member is moving in a lancing direction to prevent the second member from becoming detached (paragraph 28, lines 3-7)

Regarding claims 7 and 9, Ramel discloses the invention substantially as claimed above, but fails to disclose the first member including a hole, and further comprising an additional hole communicating with the first hole.

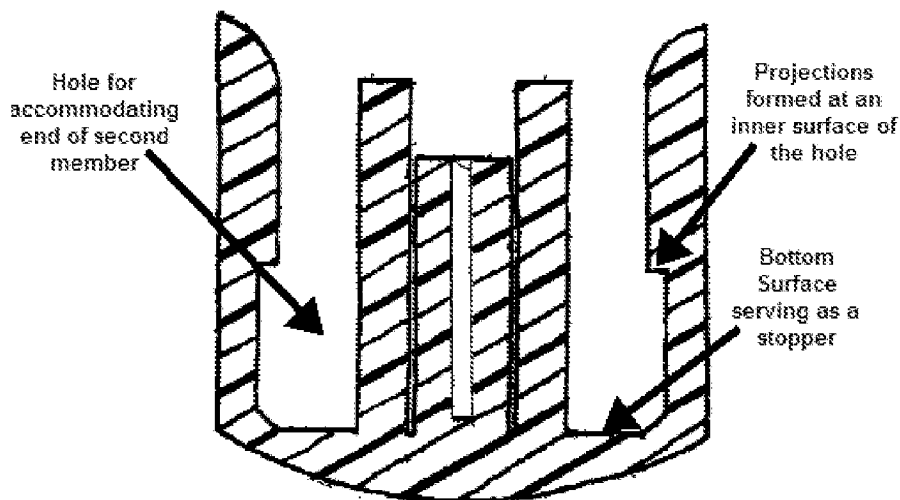
However, Searle et al. teaches a hole in the first member for accommodating an end of the second member and allowing movement of the second member; wherein the projections are formed at an inner surface of the hole (See Figure below), and the device is capable of applying force to the second member via the additional hole..



It would have been obvious to one having ordinary skill in the art at the time the invention was made to accommodate the second member in a hole in the first member to allow for the second member to be slidably coupled to the first member (paragraph 7, lines 3-6).

Regarding claim 8, Ramel discloses the invention substantially as claimed above, but fails to disclose the hole having a bottom surface serving as a stopper.

However, Searle et al. teaches a hole having a bottom surface serving as a stopper for controlling the movement of the second member (see Figure below; Figure 8)



It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the bottom surface of the hole be a stopper to allow the lancet to reach a fully extended position without having the needle puncture the patient too deeply (paragraph 26, lines 17-20)

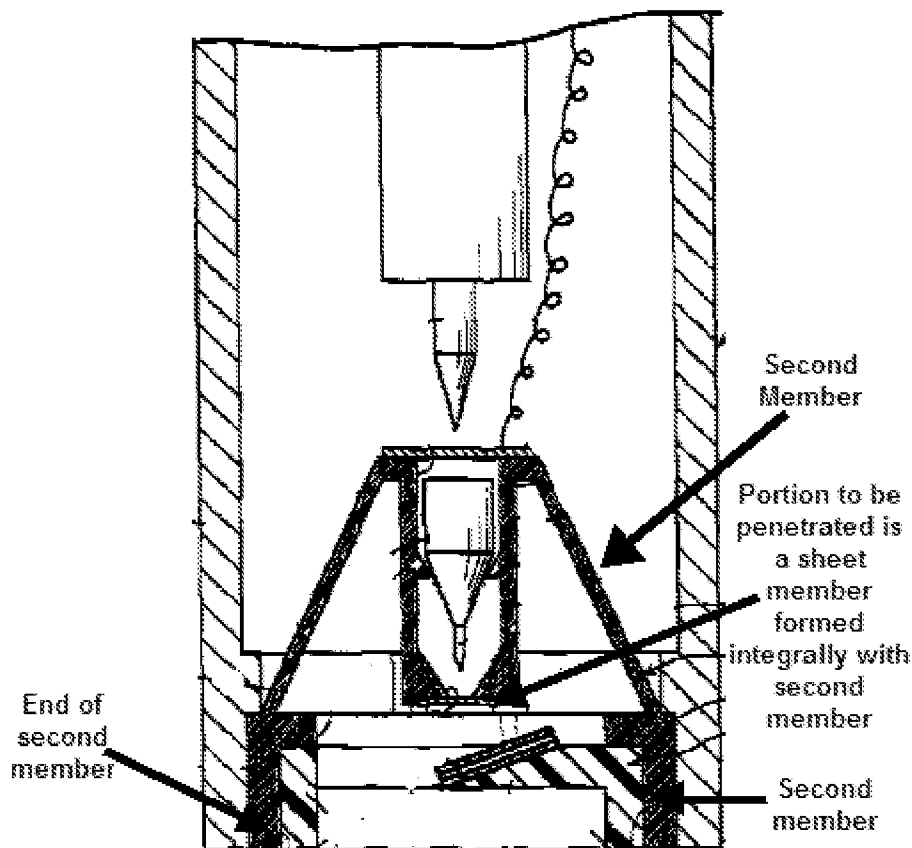
12. **Claims 10-13** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Ramel (US 5,540,709)** in view of **Hamamoto (US 7,250,056)**.

Regarding claims 10-13, Ramel discloses the invention substantially as claimed above, but fails to disclose the tip of the lancing element in a hermetically sealed state formed by an integrally formed sheet member attached to the second member.

However, Hamamoto teaches the lancing element (47) accommodated in a hermetically sealed state, and includes a portion (44b) to be penetrated by the tip of the lancing element (column 8, lines 56-60; Figures 5A-5C). The portion to be penetrated is integrally formed (welded) with the second member and provided by a sheet member (thin metal film or resin sheet) (column 4, lines 5-9), and wherein a portion to be penetrated is provided at a position retreating in a direction opposite to the lancing

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direction (Figure 3). Furthermore, the portion to be penetrated is set back from the end of the second member in a direction opposite of the lancing direction (see Figure below)



It would have been obvious to one having ordinary skill in the art at the time the invention was made to hermetically seal the lancing element to prevent deterioration and contamination of the lancet (paragraph 88, lines 3-10).

13. **Claim 15** is rejected under 35 U.S.C. 103(a) as being unpatentable over **Searle et al (US 2002/0087180 A1)** in view of **Ramel (US 5,540,709)**.

Regarding claim 15, Searle et al. discloses the mover moved in the lancing direction to engage with the second member and moves the second member relative to

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the first member in the lancing direction (paragraph 26, lines 7-22) but fails to disclose thereafter pushing the lancet out of the lancet holder.

However, Ramel et al. teaches a lancet holder (clips and arms; 20 and 18), which the lancet is pushed out of during use of the device (column 3, lines 26-32).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to push the lancet out of the holder to allow for the used lancet to be disposed of properly.

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JULIE A. SZPIRA whose telephone number is (571) 270-3866. The examiner can normally be reached on Monday-Thursday 9 AM to 6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Julie A Szpira/
Examiner, Art Unit 3731

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3731